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EXAMINER	
HEYER, DENNIS	
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1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,695	ONER ET AL.	
	Examiner	Art Unit	
	DENNIS HEYER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Applicant's remarks and amendments filed April 16, 2009. Acknowledgement is made of Applicant's addition of a new independent Claim, Claim 11 in the response filed April 16, 2009. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1 – 11 are currently pending

New and/or Maintained Rejections

New Rejection

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over USLU (WO 03/043641, see PTO/SB/08) in view of WATANABE *et al.* (US 2002/0150624, see PTO-892) and in view of BLACK *et al.* (US 2001/0051636, see PTO-892) and evidenced by TRITTHART *et al.* (US 6,242,002 see PTO-892).

This rejection is necessitated by the addition of newly added Claim 11 in the response filed April 16, 2009.

As noted in the rejection of instant Claim 10 in the non-final office action filed December 29, 2008, the combination of USLU, WATANABE and BLACK teach the limitations of instant Claim 11. Specifically, USLU teaches a pharmaceutical formulation administered orally containing alendronate mixed with alginates such as alginic acid or sodium alginate as a powder in granule form (page 6 lines 1 – 8). The alginic acid is used in amounts sufficient to prevent esophageal reflux ('a therapeutically effective amount'; page 2 lines 22 – 27). Regarding the limitation that alendronate is present as

microparticles, USLU is silent on this limitation, teaching that the alendronate composition is prepared as granules (page 5, lines 13 – 16, Claim 14). The term 'microparticles' is not defined in the instant specification and no particle size range is recited. Accordingly, absent a definition or a specific size range for the instantly claimed 'microparticles' it is the position of the Examiner that the granules of USLU are not distinguished from the microparticle limitation of instant Claim 11. The USLU reference does not teach a coating for the alginates, accordingly it is the position of the Examiner that the alginates of USLU are uncoated. USLU teaches that the active alendronate composition is prepared by a wet granulation procedure (an aggregation) in which, preferably polyvinylpyrrolidone (PVP) is used (page 5, lines 14 – 21). The limitation on colloidal silica is met by USLU who teaches excipients such as aerosil (colloidal silica) are used in the formulation (page 5 lines 2 – 6).

USLU does not teach the use of coating polymers for alendronate or sweeteners for sachet dosing.

WATANABE teaches pharmaceutical compositions for oral use that use the polymer EUDRAGIT EI00 (i.e. poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) in a 1:2:1 ratio) as a coating to improving taste masking, moisture resistance and particularly in the case of bisphosphonates, such as alendronate, improving solubility and adsorption (paragraphs [0005], [0016], [0017] and [0028]; Example 1). The polymer is soluble at gastric pH juices, which reads on gastric pH of 1 – 4 and implied from its taste masking properties, insoluble at salivary or esophageal pHs, which reads on pHs of 6 – 7.5.

BLACK teaches the use of bisphosphonates, such as alendronate in sachets with sweetening agents (paragraphs [0032], [0110] and [0111]). TRITTHART teaches sweeteners such as saccharin and sucrose are commonly used in sachets to improve flavor and taste (Claims 2 and 16). TRITTHART also teaches that sachets are useful forms for adapting formulation to be dissolved in water before being taken (Claim 2).

Instant Claim 11 contains limitations directed to the *properties* of the formulation, specifically, b) that the "alendronate dissolves in 900 ml 0.1 N HCl at the rate of not less than 85% of within 30 minutes at the range of pH 1 – 4, and, c) that the dispersion in a glass of 250 ml. water at the degree of 25°C contains no dissolved alendronate at pH 6 – 7.5 or at the most 10% w/v of alendronate dissolved in 3 minutes." As Applicants' structure and composition are the same as in the prior art, the *properties* of the composition are the same. The burden of proof is thus shifted to applicant to demonstrate that the composition taught in the prior art, as disclosed by the cited references, would not provide the properties recited within the limitation of instant Claim 11. See: In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). See MPEP § 2112- 2112.02.

Further, instant Claim 11 contains limitations drawn to the process by which the composition is prepared. For examples: "microparticles aggregated with polyvinylpyrrolidone dissolved in ethanol" and "said polymer in admixture with ethanol, acetone". The patentability of product-by- process limitations within a claim is based on the product itself. "[E]ven though product-by-process claims are limited by and defined

by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698,227 USPQ 964,966 (Fed. Cir. 1985). MPEP § 2113 states "[o]nce the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)." Where the end products are the same, the process of making limitations do not have to be given weight in ex parte examination. See Atlantic Thermoplastics Co. v. Faytex Corp., 23 USPQ2d 1481, 1490-91 (Fed. Cir. 1992).

Finally, elements of instant Claim 11 are drawn to an intended use of the instantly claimed composition ("to prevent esophegeal reflux, heartburn and esophagitis). The recited intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use (prevention of esophegeal reflux, heartburn and esophagitis), then it meets the claim (MPEP 2111.02, II).

Thus, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to make a sachet formulation comprising

alendronate microparticles coated with a polymer insoluble at pH 6 – 7.5, such as EUDRAGIT EI00 and alginic acid or sodium alginate with sweeteners, as taught by USLU in view of WATANABE in view of BLACK and evidenced by TRITTHART. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because of the beneficial effects of improved taste, moisture resistance and particularly in the case of bisphosphonates, such as alendronate, improved solubility and adsorption for the treatment of bone disorders, as taught by WATANABE and the improved taste with sucrose and saccharin in sachets which allow for easy dispersal in water before administration as taught by BLACK and evidenced by TRITTHART. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Maintained Rejections

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over USLU (WO 03/043641, see PTO/SB/08) in view of WATANABE et al. (US 2002/0150624, see PTO-892) and in view of BLACK et al. (US 2001/0051636, see PTO-892) and evidenced by TRITTHART et al (US 6,242,002 see PTO-892).

USLU teaches a pharmaceutical formulation administered orally containing alendronate mixed with alginates such as alginic acid or sodium alginate as a powder in granule or microparticle form. See e.g. p6 lines 1-8: instant claims 1 and 10. The alginic acid is used in amounts sufficient to prevent esophageal reflux. See e.g. p2 lines 22-27. The alendronate, in the form of alendronate sodium (pharmaceutical derivative of alendronate monosodium trihydrate see p2 lines18-20) is used to prevent loss of calcium in bones with amounts ranging from 5-40mg/day or 35-70mg/week. See e.g. p3 lines 8-15: instant claim 8. The alginates are uncoated and used in amounts ranging from l mg to 2000mg. See e.g. p5 lines 1-4: instant claims 1 and 10. A ratio of alginates to alendronate in USLU reads on the percents of alendronate (0.001% to 3%) and

alginates (0.001% to 2 %) in the instant, i.e. a 1:1 to 2:3 ratio give the stated percents: instant claims 7 and 9. Lubricants, glidants, fillers and excipients such as aerosil (colloidal silica) and microcrystalline cellulose are used in the formulation. See e.g. p5 lines 2-6: instant claims 2, 3 and 10. The microcrystalline cellulose is used between 10% and 200% of the alginates or between 10% and 1000% of the alendronate. See e.g. p5 lines3-4 and 23-24.

USLU does not teach the use of coating polymers for alendronate or sweeteners for sachet dosing.

WATANABE teaches pharmaceutical compositions for oral use that use the polymer EUDRAGIT El00 (i.e. poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) in a 1:2:1 ratio) as a coating to improving taste masking, moisture resistance and particularly in the case of bisphosphonates, such as alendronate, improving solubility and adsorption. See e.g. pp[0005], [0016], [0017] and [0028] and Example 1: instant claims 1, 5, 6 and 10. The polymer is soluble at gastric pH juices, which reads on gastric pH of 1-4 and implied from its taste masking properties, insoluble at salivary or esophageal pHs, which reads on pHs of 6-7.5: instant claims 1 and 10. See e.g. p[0016].

BLACK teaches the use of bisphosphonates, such as alendronate in sachets with sweetening agents. See e.g. p[0032], [0110] and [0111]: instant claim 1. Specific sweeteners for use in sachets are evidenced by TRITTHART which teaches sweeteners such as saccharin and sucrose are commonly used in sachets to improve flavor and taste. See e.g. claims 2 and 16: instant claim 10. TRITTHART also teaches that sachets

are useful forms for adapting formulation to be dissolved in water before being taken. See e.g. claim 2.

Claims 1, 7, 9 and 10 contain language directed to the properties of the formulation, specifically in claims 1 and 10 that the "alendronate dissolves in 900 ml 0.1 N HCl at the rate of not less than 85% of within 30 minutes at the range of pH 1 - 4, and the dispersion in a glass of 250 ml. water at the degree of 25°C contains no dissolved alendronate at pH 6 - 7.5 or at the most 10% w/v of alendronate dissolved in 3 minutes." and claims 7 and 9 whereby the formulation disperses in a glass of 250 ml water at the degree of 25°C at pH 6 - 7.5. Applicants' composition, as claimed, is the same as the prior art. As claimed, Applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. In re Fitzgerald, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. In re Best, 195 USPQ 433.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to make a sachet formulation comprising alendronate microparticles coated with a polymer insoluble at pH 6 - 7.5, such as EUDRAGIT El00 and alginic acid or sodium alginate with sweeteners, as taught by USLU in view of WATANABE in view of BLACK and evidenced by TRITTHART. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because of the beneficial effects of improved taste,

moisture resistance and particularly in the case of bisphosphonates, such as alendronate, improved solubility and adsorption for the treatment of bone disorders, as taught by WATANABE and the improved taste with sucrose and saccharin in sachets which allow for easy dispersal in water before administration as taught by BLACK and evidenced by TRITTHART. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Response to Arguments

Applicant's arguments filed April 16, 2009 with respect to the rejection under 35 U.S.C 103(a) of Claims 1 – 10 as being unpatentable over USLU (WO 03/043641) in view of WATANABE et al. (US 2002/0150624) and in view of BLACK et al. (US 2001/0051636) and evidenced by TRITTHART et al (US 6,242,002) have been fully considered but are not found to be persuasive.

Applicant contends that the instantly claimed composition is distinguished from that taught by the prior art references as the references do not teach the limitation that the alendronate is a microparticle (cited numerous times in the response filed on April1 6, 2009; see for example: page 8, page 9, 1st paragraph, page 11, 2nd paragraph). Further, with respect to the USLU reference, Applicant argues (page 8, response filed April 16, 2009) that the USLU reference, fails to disclose a formulation comprising alendronate in a working example, for oral administration, except for reference to a tablet or capsule, and finally, that the preferred formulation is a double layer tablet.

Further, Applicant argues that a microparticle formulation of alendronate in a sachet formulation is neither disclosed nor suggested by USLU and that the bisphosphonate is uncoated.

In response, the Examiner will first comment on Applicant's arguments that the prior art references, specifically USLU, do not disclose alendronate as microparticles. The Examiner agrees with Applicant, Uslu discloses granules of bisphosphonate (see, for example: page 5, lines 13 – 16, Claim 14) and does not explicitly disclose microparticles. Applicant, on the other hand, discloses and claims compositions comprising alendronate microparticles but fails to offer a special definition of microparticles or a preferred particle size range (typically such a limitation is recited in microns or mesh size). Accordingly, absent a range of particle size, or any specific evidence to the contrary, it is the position of the Examiner that the granules of alendronate taught by Uslu, meet the limitation of 'microparticles' disclosed and claimed by Applicant.

Applicant's arguments that Uslu fails to disclose a working Example with alendronate or that the disclosure is directed to *any* bisphosphonate (response, page 8) is not relevant to a 103 rejection as Uslu clearly discloses alendronate as one of three bisphosphonates. One of ordinary skill would clearly identify alendronate as a bisphosphonate suitable for the formulation taught by Uslu.

Applicant argues that Uslu fails to disclose a coating for alendronate. In response it is noted that this represents an argument against a reference individually and one cannot show nonobviousness by attacking references individually (Uslu) where

the rejections are based on a combination of references (Uslu and Watanabe). See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The *combination* of Uslu and Watanabe, as noted in the rejections of instant Claims 1 – 11 above, provide a *prima facie* case for coating the granules of Uslu with Eudragit E100 in order gain benefit of, for example, improved drug absorption.

Applicant's argument that the Uslu reference is deficient in that it teaches alginic acids to treat esophegal reflux only in the background section of the reference are not relevant. The teaching that alginic acids are used to treat esophegal reflux is relevant regardless of where it is taught in the reference as this property will not be any different depending on where in a reference it is disclosed. Further, it is not a property of alginic acid that is used as a basis for the rejection but the composition (alginic acid and alendronate) disclosed by Uslu.

Argument's by Applicants that the disclosed dose ranges for alginate and alendronate are a) broad, b) taught in the background section and, c) disclosed, but not Claimed, by Uslu are all not relevant to a 103 rejection. The dose ranges for alendronate and alginate recited by Uslu fall within the instantly Claimed ranges. See MPEP 2144.05: In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

Applicant's argument that Uslu reference teaches a 1:5 to 1:1 range of bisphosphonate to alginate is not relevant as it teaches the lower end of the instantly claimed range (1:1). See MPEP 2144.05 above.

Applicant's arguments that Uslu does not teach the benefits of a sachet formulation (page 11, response) are not relevant as this represents an argument against a reference individually and one cannot show nonobviousness by attacking references individually (Uslu) where the rejections are based on a combination of references (Uslu and Black as evidenced by Tritthart). See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The combination of Uslu, Black and Tritthart, as noted in the rejections of instant Claims 1 – 11 above, provide a *prima facie* case for a sachet formulation regardless of whether the motivation cited in the response by Applicant (page 11) is the same as that recited in the prior art. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

With respect to the Watanabe reference, Applicant argues that Watanabe uses the Eudragit coating to, for example, increase absorption of alendronate and to mask a bitter taste. Applicant contends that there would be no motivation to combine the Eudragit coating with the alginate/alendronate composition of Uslu for such intended uses as Uslu employs alginate/alendronate to prevent esophegal reflux. In response the Examiner notes that first, it is alginate that is used to prevent esophegal reflux.

Second, the increased absorption and masking of bitter tastes conferred by Eudragit, as taught by Watanabe, are desired benefits of an alginate/alendronate composition and thus it would have been *prima facie* obvious to combine the Uslu and Watanabe references for these reasons.

With respect to the Black and Tritthart references (response, page 13 - 14), Applicant argues that these references do not teach their specific intended use of a sachet, the prevention of destruction of the coated alendronate microparticles, and Tritthart teaches only that sachets are useful forms for dissolving a formulation in water. Applicant admits that this 'intended use' of a sachet formulation is common knowledge. In response to applicant's argument that Tritthart does not teach Applicant's intended use of a sachet formulation, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure (uncoated alginate/coated alendronate in a sachet formulation) is capable of performing the intended use, then it meets the claim. Applicant has provided no evidence that the prior art structure is incapable of performing Applicant's intended use.

Finally, the Examiner will address Applicant's comments regarding the legitimacy of cited reference WO 03/043641 (Uslu) as prior art. Applicant argues that one could not have been motivated to combine features of the Uslu reference as this reference was not published until May 30 2003, which is after the date, April 18, 2003, Applicant filed their application. In response the Examiner points out that the WO document was

filed October 15, 2002, in English and designated the United States. Accordingly , the reference qualifies as a prior art under U.S.C. 35 section 102(e). See MPEP: 2136.

Conclusion

Claims 1 – 11 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615